IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO: **THE WAVE 4 CASES LISTED IN EXHIBIT A**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF SCOTT A. GUELCHER

Plaintiffs submit the following Memorandum of Law in opposition to the "Motion to Exclude the Opinions and Testimony of Scott Guelcher, Ph.D." filed by Defendants Ethicon, Inc. and Johnson & Johnson (collectively "Ethicon or Defendants"). Dr. Guelcher's opinions on alternative design are based in principles of engineering and the foreign body response to Ethicon's polypropylene-based mesh products. As such, his opinions are focused on what the literature states about the unnecessary and excessive foreign body response to Ethicon's polypropylene-based mesh products when compared to other products that are used to treat the same underlying conditions. His opinions are completely reliable and recount unquestioned facts about Ethicon's mesh products and several alternative designs.

Ethicon's Wave 4 Motion only seeks to exclude opinion testimony from Dr. Guelcher about safer alternative designs and any opinions that he may have about Ethicon's purported knowledge or state of mind. Ethicon only attacks the nature of the alternative designs Dr. Guelcher puts forth and cite a lack testing or support in the literature for his opinions. Ethicon

never once argues that Dr. Guelcher's opinions are not relevant or accurate. For the reasons below, this Court should reject all of these arguments. [1]

ARGUMENT

A. Dr. Guelcher has offered proper alternative designs to Ethicon's kit-based mesh products.

Defendants argue that surgical non-mesh repair—"in which the only device at issue is a simple surgical suture"—cannot constitute an alternative design.[2] But this argument fails. First, Ethicon's above statement is an admission that products like its surgical sutures are medical devices that can be used to suspend human tissues for the purpose of accomplishing the same goals as its mesh products. Second, Ethicon makes no mention that its sutures come with instructions for use and require FDA involvement to be sold for permanent surgical implantation.[3] And finally, Ethicon ignores the fact that its entire suture line of products (including Prolene sutures) are sold with needles that "are permanently attached to the suture materials, eliminating the need for threading and providing a new, sharp needle each time."[4]

What all of this means is that Ethicon's surgical sutures with permanently attached needles—the same sutures that are used in the Burch and tissue suspension procedures—are, in fact, analogous to the needle passers and trocars that are attached to the meshes in the kits at issue in this litigation. The only difference between the suture products and kit products is how they are utilized to treat the underlying condition: suture products suspend tissues into

[1] For the sake of brevity and because the Court is fully aware of the legal standards governing the admissibility of expert testimony in the Fourth Circuit, Plaintiffs will not set forth a detailed discussion of the legal standard. Plaintiffs incorporate by reference standard of law previously articulated by the Court in this litigation. *See* Mem. Op. and Order (*Daubert* Motion re: Scott Guelcher, Ph.D.), No. 2:12-md-02327, at 5-6 (S.D. W. Va. Aug. 31, 2016) [doc. 2788].
[2] Defs' Brief at 2.
[3] In fact, Ethicon has repeatedly pressed the (failed) argument that the FDA's prior approval of its Prolene suture device affords certain legal protections to the transvaginal devices at issue in these cases.
[4] https://woundclosure.ethicon.com/sites/com.wcrc_v2_rest/files/ethicon-catalog.pdf at 6 and 202-227 (page last accessed 4/27/17)

anatomical position and the kit products act as a scaffold to hold up those same tissues. Indeed, there is nothing 'simple' about Ethicon's sutures and they meet all the criteria necessary to be considered an alternative design to Ethicon's mesh products.

Moreover, Ethicon's Motion cherry-picks rulings that have not been applied to the facts here, nor can they be applied to the entire of Wave of cases before this Court. Indeed, in *Mullins*, a West Virginia-specific determination, this Court wrote "[o]nce the court determines that the plaintiffs have provided sufficient evidence to identify a comparable product or design concept, whether the design features of the comparable product or the design concept existing at the time of the TVT's manufacture is an alternative, feasible design for the TVT is a factual question left to the jury." *Mullins v. Johnson & Johnson*, No. 2:12-CV-02952, 2017 WL 711766, at *2-3 (S.D. W. Va. Feb. 23, 2017). This ruling applies only to cases arising out of the state of West Virginia, and it leaves the ultimate determination of fact up to the jury. Ethicon's argument, therefore, that sutures or biologic products are not alternative designs cannot be applied to the entirety of Wave 4 and, therefore, the Motion must be denied at this time.[5]

Ethicon also mistakenly argues that "[a]t bottom, Dr. Guelcher's opinion is that mesh is defective because it undergoes oxidative degradation in vivo and elicits an increased foreign body reaction, meaning that no medical device composed of synthetic material for the treatment of SUI or POP is an appropriate treatment option."[6] But Dr. Guelcher has never stated that *no* synthetic material could be used in the pelvic floor—what he takes issue with is the use of polypropylene mesh *specifically* in this application.[7]

[5] This Court did not have the additional similarities detailed between Ethicon's own Prolene sutures and its mesh products (sutures with attached needles are analogous to mesh with attached trocar/needle passers), detailed before it in the *Mullins* litigation, the Plaintiffs respectfully ask that it considers them for the purposes of this Motion.
[6] Def.'s Br. at 3.
[7] Exhibit B at 8, 12-22.

Ethicon's reliance on *Theriot v. Danek Medical, Inc.,* 168 F.3d 253 at 255 (5th Cir. 1999), is therefore, completely misplaced. In *Theriot*, the Fifth Circuit held that the "[u]nderlying [plaintiff's] argument is the *assumption* that all pedicle screws are defective and there can be no system using pedicle screws that would be an acceptable product" and that "[t]he problem with this argument is that it really takes issue with the choice of treatment made by [plaintiff's] physician, not with a *specific fault* of the pedicle screw sold by [manufacturer]."[8] Here, Dr. Guelcher makes no *assumption* that all synthetic meshes are faulty—as Ethicon argues—and instead he *finds fault* with using polypropylene-based meshes in this application. No mention of using other synthetic meshes is made in his report.[9] And, indeed, he is even advocating for the use of synthetic sutures (including Prolene sutures) to hold biologic products in place or to suspend the appropriate tissues as alternative designs to using polypropylene mesh.

There is, therefore, nothing argued in Ethicon's motion that would preclude Dr. Guelcher from offering opinions that suture-based repairs and biologic repairs are safer alternatives to using polypropylene mesh. He finds fault specific to the use of polypropylene mesh here and he is offering a readily available alternative to it. As such, the Motion should be denied.

B. Dr. Guelcher's alternative design opinions are reliable.

1. The Fourth Circuit's Opinion in *Nease* does not change the Court's analysis.

There is nothing in Ethicon's discussion of the recent decision out of the Fourth Circuit (*Nease v. Ford Motor*) that changes how the Court analyses reliability of Dr. Guelcher's alternative design opinions.[10] Indeed, the very passages from *Nease* relied upon by Ethicon in

[8] *Id*., emphasis added.
[9] See Exhibit, B, generally.
[10] Defs' Motion at 4-6; *see also Nease v. Ford Motor Co*., 848 F.3d 219, 231 (4th Cir. 2017).

relation to *Daubert* standards, including the court's discussion of "testing," are for the most part direct quotes taken from prior—sometimes decades-old—Fourth Circuit opinions.[11]

"Testing," however, has long been a factor considered by courts when considering the reliability of an expert's opinion. But there is no *requirement*, in *Nease* or elsewhere, that an expert must perform testing on a product—it is just one of the factors taken into account. Indeed, as the Fourth Circuit reiterated in *Nease*, an expert may support his or her opinions through "evidence such as test data[12] *or relevant literature in the field*." *Nease*, 848 F.3d at 231 (emphasis added).

Plaintiff's expert in *Nease* primarily relied upon a Ford FMEA that did not even apply to the model year of the car (2001 Ford Ranger) at issue. *Nease*, 848 F.3d at 224-25, 226, 232. Moreover, he acknowledged that: (1) during his examination of the plaintiff's car, he did not observe the conditions he opined could result in the malfunction; (2) the part at issue in plaintiff's car operated correctly during his examination of it; and (3) he had never—in plaintiffs' car or any other car—observed the defective condition he claimed could exist. *Id.* at 225-226, 231-32. In fact, plaintiff's expert could not even distinguish a working part from a non-working part in videos shown to him during trial. *Id*. at 226.

Here, Dr. Guelcher relies upon his experience in biomaterials, Ethicon's internal studies on mesh and Prolene specifically, all of the clinical literature about the foreign body response to polypropylene sutures and mesh, and many clinical papers comparing the use of biologics and other suture repairs to that of polypropylene mesh. His alternative design opinions are

[11] See e.g., Def's Brf. at 4-6 (citing *Nease* quoting *Oglesby v. Gen. Motors Corp*., 290 F.3d 244, 249 (4th Cir. 1999)).

[12] In *Nease*, the court merely focused on plaintiff's expert's lack of testing of the purported defect because there was no other support provided. *Id.* at 231 ("Testing was of critical importance *in this case*….) (emphasis added).

completely grounded in the clinical and scientific literature. All of which sets him apart from the expert in *Nease*.

2. Dr. Guelcher has support in the literature for his alternative design opinions.

In *Nease*, unlike here, the plaintiff's expert's theories were completely hypothetical and without support. The opinions that Dr. Guelcher is offering about alternative designs are all based on measurable data with repeatable results from countless scientific experiments, decades of clinical usage and scientific study, and many papers that are recounted in his report.[13] Indeed, while Defendants' Motion admits that Dr. Guelcher's report contains all of these things, Ethicon says they are not enough because he only cites to a handful of papers where his alternative designs are actually compared to the safety and efficacy of using polypropylene mesh. But this criticism rings hollow since it overlooks the fact that over thirty papers on alternative design are listed in his reliance material. And while Ethicon also argues that Dr. Guelcher has not reviewed any papers on prolapse repair, a cursory review of his reliance list shows that not to be true; the word prolapse appears in the titles of fourteen different articles—many of which are discussing the benefits of suture and/or biologic repair over synthetic mesh.[14]

3. Dr. Guelcher has reviewed and relied on the scientific and clinical literature related to mesh repair in the female pelvis.

Similarly, Ethicon argues that Dr. Guelcher's opinions should be excluded since he has not reviewed the vast majority of papers describing the kinds of problems associated with using mesh to repair the pelvic floor, but this is not the case. Instead, Dr. Guelcher's reliance material, while it does not contain "vast majority" of articles describing polypropylene mesh repair for the pelvic floor, he cites and has relied upon many such papers to hold his opinions. Importantly, he is not opining as a medical professional—but as an engineer with expertise in the foreign body

[13] Exhibit C, Guelcher Reliance
[14] *Id*.

reaction to polypropylene mesh and with respect to many other materials. As such, his opinions are fully supported by his experience, expertise, and the available scientific and clinical literature under the *Daubert* analysis.

C. Dr. Guelcher will not be opining on corporate intent.

Counsel for Ethicon correctly points out that this Court has previously disallowed experts to testify regarding a corporation's knowledge or state of mind. Dr. Guelcher only intends to testify as to Ethicon corporate documents at trial for the purpose of explaining the basis for his opinions, in accordance with this Court's previous ruling on this issue.[15]

CONCLUSION

Ethicon's Motion seeks to undermine Dr. Guelcher's well-reasoned and supported opinions on alternative design. The scientific literature supports his opinions and the arguments made that challenge their reliability have no merit. For the reasons above, Defendant's Motion to Exclude the Testimony and Opinions of Dr. Scott Guelcher, Ph.D. should be denied in its entirety.

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Respectfully submitted,

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[15] *Huskey*, 29 F. Supp. 3d 691.

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CERTIFICATE OF SERVICE

I hereby certify that on April 27, 2017, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Michael H. Bowman